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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,630

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EXAMINER

JACOBSON, MICHELE LYNN

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

05/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,630	<b>Applicant(s)</b> WIDERSTROM, CARIN	
	<b>Examiner</b> MICHELE JACOBSON	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/19/05</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The scope of claim 2 is unclear and therefore indefinite as to whether “bonding layer is preferably of polyethylene” and “sealing layer is preferably a low density polyethylene” is a limitation to the claims or is merely suggestive of a preferred embodiment. For the purpose of examination claim 2 will be interpreted to include the limitations of the “bonding layer is polyethylene” and the “sealing layer is low density polyethylene”. Appropriate correction is required.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

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question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 10 and 11 recite the broad recitations “wherein the sealing layer iv) has a weight per unit area of 10-100 g/m<sup>2</sup>” and “wherein said barrier layer iii) has a thickness of 6-30 μm” respectively, and the claims also recite “more preferred 15-75 g/m<sup>2</sup>, preferably 20-50 g/m<sup>2</sup>, more preferably 30-40 g/m<sup>2</sup>, most preferred 35 g/m<sup>2</sup>” and “7-25 μm, preferably 9-25 μm, more preferred 8-20 μm, preferably 9-15 μm, more preferred 12 μm” respectively which is the narrower statement of the range/limitation. For the purpose of examination claims 10 and 11 will be interpreted to encompass the broadest ranges as limitations. Appropriate clarification is required.

### ***Claim Rejections - 35 USC § 112/101***

5. Claims 15 and 16 provides for the use of a sachet, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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6. Claims 15 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

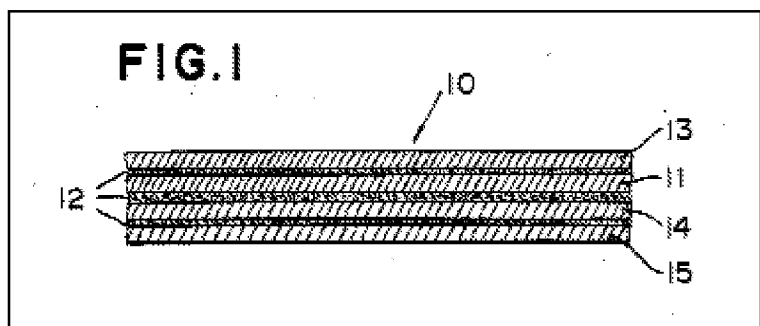
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-7 and 9-14 rejected under 35 U.S.C. 102(b) as being anticipated by Asakura et al. U.S. Patent No. 4,360,550 (hereafter referred to as Asakura).

9. Asakura teaches a packaging pouch for packing materials such as medicines comprising a laminate film. (Col. 1, lines 8-13, Fig. 1) The laminate film comprises a base film (11) of paper or aluminum foil. When paper is used the thickness is recited to be in the range between 40-90 g/m<sup>2</sup>. (Col. 3, lines 63-66) When Al foil is used,



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the thickness is recited to be in the range of between 7 to 30  $\mu\text{m}$ . (Col. 4, lines 5-8)

10. The base layer (**11**) is recited to be adhered between two HDPE layers, (**13**) and (**14**), having a thickness between 10-50  $\mu\text{m}$ . (Col. 4, lines 9-23) A sealant layer (**15**) comprising low density polyethylene in a thickness between 15 to 120  $\mu\text{m}$  is laminated on one of the HDPE layers. (Col. 5, lines 25-53) Adhesive layers, (**12**), are disposed between all of the layers of the laminate.

11. Regarding claim 1: Applicant's claim 1 recites a sachet comprising four layers, but does not specify what order the layers are required to be in. As such, layers 13 and 14 of Asakura are interpreted to read on layers iii) barrier layer and ii) bonding layer respectively. The examiner also reasonably broadly interprets the recitation of "sachet" to read on a pouch. As such, Asakura clearly anticipates a laminate comprising a paper layer, bonding layer, barrier layer and sealing layer as claimed in claim 1.

12. Regarding claims 3-5: Asakura clearly recites that the paper layer have a weight per unit area of 40-90  $\text{g/m}^2$ . The recitation of 40  $\text{g/m}^2$  anticipates points within all of the ranges recited in claims 3-5.

13. Regarding claims 6 and 7: The HDPE layer (**14**) is interpreted by the examiner to read on the bonding layer claimed. This layer is recited to be between 10-50  $\mu\text{m}$  thick and comprise a polymer with a density greater than 0.94  $\text{g/cm}^3$ . When converted, a layer of such a thickness comprising such a polymer has a weight per unit area of between 9.4  $\text{g/m}^2$  and 47  $\text{g/m}^2$ . 9.4  $\text{g/m}^2$  anticipates data points within the ranges claimed in claims 6 and 7.

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14. Regarding claims 9 and 10: Asakura clearly recites that the sealing layer be between 15-120  $\mu\text{m}$  thick which anticipates a data point in the range claimed in claim 9. The sealing layer is recited to comprise an LDPE with a density less than  $0.92 \text{ g/cm}^3$ . When converted for a layer 15  $\mu\text{m}$  thick, the LDPE sealing layer would have a mass per unit area of 13-8  $\text{g/m}^2$ , which anticipates a data point within the range claimed in claim 10.

15. Regarding claim 11: The HDPE layer interpreted by the examiner to read on the barrier layer iii) of claim 1 is recited to be between 10-50  $\mu\text{m}$  thick which anticipates a point within the range claimed in claim 11.

16. Regarding claims 12-14: Asakura clearly recites that the pouch of the invention is useful for medicines which is interpreted by the examiner to read on the pharmaceutical formulations claimed in claim 12. While there is no disclosure that the pouch disclosed by Asakura is used for mesalazine or a pharmaceutically acceptable salt thereof as presently claimed, applicants attention is drawn to MPEP 2111.02 which states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the *purpose or intended use results in a structural difference between the claimed invention and the prior art*. Only if such structural

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difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

17. It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. packaging mesalazine or a pharmaceutically acceptable salt thereof, recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art pouch disclosed by Asakura and further that the prior art structure which is a pouch identical to that set forth in the present claims is capable of performing the recited purpose or intended use. Therefore, the invention of Asakura reads on the limitations of claims 13 and 14.

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. U.S. Patent No. 4,360,550 (hereafter referred to as Asakura).

20. Asakura teaches what has been recited above, but is silent regarding using an Al foil layer and paper layer simultaneously.



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21. It is well known in the polymer packaging arts that Al foil layers provide excellent barrier properties to laminates. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included an Al foil layer in addition to the paper layer recited by Asakura to produce a laminate with good dimensional stability and excellent barrier properties. Such a laminate comprising a paper layer, an Al foil layer, an HDPE layer and an LDPE sealing layer would have been the same as the laminate claimed in claim 2.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Thursday 8:30 AM-7 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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